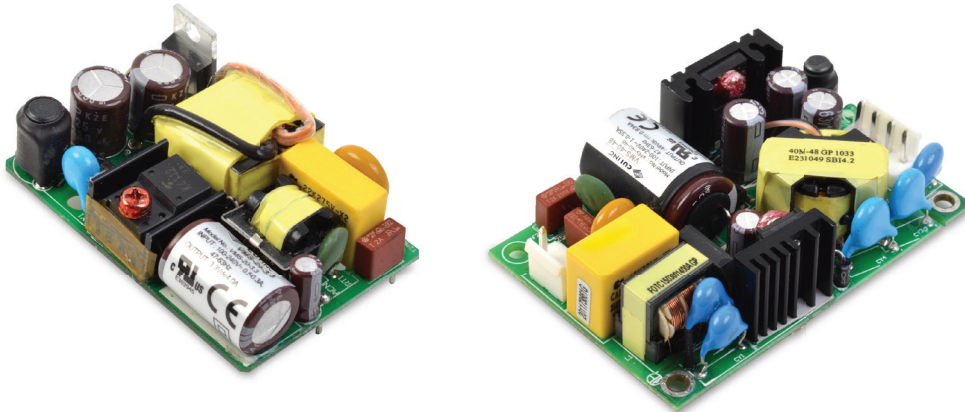


IEC 60601-1 Medical Design Standards-3rd Edition



Standards are an integral part of product design and development, and are clearly important in medical applications. However, there is an additional aspect to standards for medical devices: while some technical standards — such as IEEE 802 for Wi-Fi — only define final performance, standards for medical design go much deeper, covering design methodology and verification, safety and risk assessment, implementation, and much more. Here we look at the medical standard IEC 60601-1 and the recent shift to the 3rd edition.

IEC 60601-1

WHAT IS IEC 60601-1

IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment.

The primary standard governing medical device design is IEC 60601-1 [medical electrical equipment - Part 1: general requirements for basic safety and essential performance]. Often referred to simply as “60601,” compliance with the standard has become a de facto requirement to bring new medical devices to market in many countries.

Many of today's products appear simple; yet embed sophisticated circuits and software that are invisible to the user. The IEC 60601-1 standard manages this reality by becoming intimately involved in the product-development process, going beyond performance test and verification. This is done because the product complexity generally yields a nearly uncountable number of potential test cases, permutations, and combinations in both normal and non-normal operating modes, and these cannot be assessed in the final design alone.

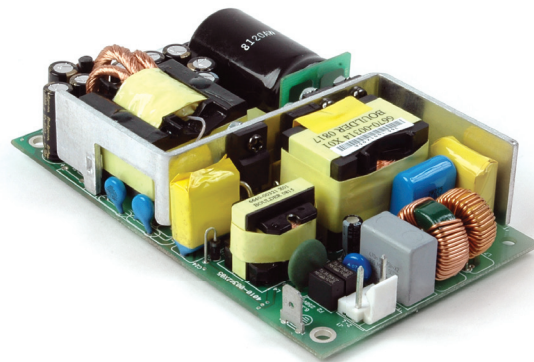


FIGURE 1: The shift to IEC 60601-1 3rd edition standards for medical devices, now in force in Europe, Canada, and the US, has significant implications for medical device design.

IEC 60601-1 EVOLUTION

The IEC 60601 standard has a long history with a number of revisions. The original IEC 60601-1 was published in 1977, and the 2nd revision was published in 1988. The 3rd edition was published by the IEC in 2005.

Because the global shift to IEC 60601-1 3rd edition is still underway, 2nd and 3rd edition standards must still coexist in equipment intended to ship internationally, creating an added level of complexity for device designers who must account for both standards.

THE 2nd EDITION

Ac-dc power supplies and dc-dc converters have always played a crucial role in the certification of medical equipment. That's understandable since the power supply is responsible for major aspects of power conversion, distribution, and protection. Physics 101 teaches us that power [seen both as current and voltage] can be hazardous if not properly managed.

In the 2nd edition, the guidelines applied when the device was within the "patient vicinity," defined as a 6-foot radius from the patient. Within this envelope, there were three categories of increasing severity: Type "B" [body] equipment operates within the vicinity, but without patient contact; Type "BF" [body floating] equipment makes physical contact with the patient; and Type "CF" [cardiac floating] makes physical contact with the heart. The classification determined what type of levels of isolation, insulation, creepage, clearance, and leakage would be mandated or allowed.

THE SHIFT TO 3rd EDITION

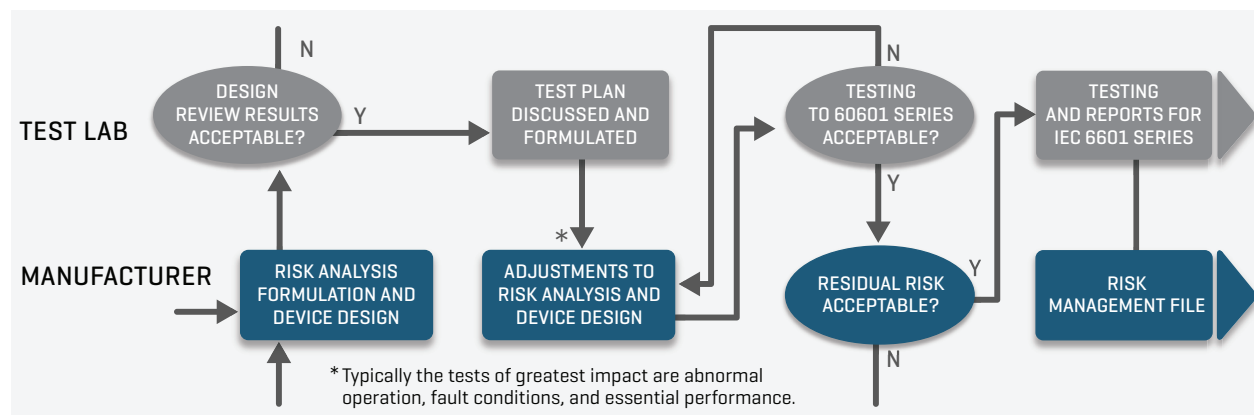
The 3rd edition changes this perspective, by requiring that the overall means of protection [MOP] be some combination of one or more means of operator protection [MOOP] and means of patient protection [MOPP].

These can be satisfied with basic safety insulation, use of protective earth ground, and isolation barriers that present a high-impedance path between input and output - of course, it may be ambiguous if a particular circuit or function falls under MOOP or MOPP categories; the manufacturer needs to assess this and record it in the risk management file.

The 3rd edition standard encompasses both hardware and software design of the completed product, and makes some fundamental changes compared to the 2nd edition.

In particular, interaction between the manufacturer and the test lab is much greater. The medical device manufacturer uses an ISO-14971 risk analysis and management process to define 1 of 4 possible MOP classifications. ISO-14971 also specifies a process to identify hazards associated with medical devices; used to evaluate associated risks, control these risks, and monitor the effectiveness of the controls.

FIGURE 2: The testing procedure has been made significantly more complex with far greater levels of external review from the test lab.



KEY CHANGES TO IEC 60601-1

- 1) "Basic Safety" is now expanded to "Essential Performance." This is the performance required to avoid unacceptable risk despite the absence of, or degradation of, a function or feature. What determines "acceptable risk" is left to the manufacturer and its documentation and analysis.

Therefore, it is critical to
 - a) establish a risk management process;
 - b) establish acceptable levels of risk; and
 - c) demonstrate that the remaining risk is acceptable.
- 2) The design process is addressed in more depth, especially for software design, since traditional hardware "failure" is not a meaningful concept [yes, software has problems, but it doesn't fail].
- 3) The standard is now organized to place greater emphasis on verification and validation of the design.

In short, the revised standard places major emphasis on risk assessment and management. It achieves this by focusing on the development process as much as, or even more than, the final product itself. The Risk Management Process [called out by 60601 and described in ISO 14971] includes a risk management file where identifiable fault conditions are identified and assessed.

GLOBAL IEC 60601-1 3rd EDITION ADOPTION

EUROPEAN UNION

The revised 3rd edition standard was adopted first by the European Union, with the member states passing legislation in 2006.

As of the June 1, 2012, the second edition has been "withdrawn" and all new and existing products need

to be certified to this new edition, known in Europe as EN60601-1:2006.

NORTH AMERICA

The timing and applicability of ANSI/AAMI ES60601-1:2005, which is the harmonized version of IEC 60601-1 3rd edition in the US, is different than the 3rd edition standard in the EU. Originally set to go into effect July 1, 2013, the FDA announced an extension to give US medical device designers a slight reprieve, setting the updated transition date to December 31st, 2013. The US standard also differs from the EU version in that only products that come to market after the transition date need meet the updated edition, existing products do not.

Canada's CAN/CSA C22.2 No. 601.1 3rd edition standard was initially released with an effective date of June 2012, but as in the US, it was delayed, with an updated transition date of April 2013. The Canadian standard also applies only to new products launched after the effective date.

REST OF THE WORLD

Some of the requirements of the 2nd edition are in potential conflict with the 3rd. Thus, complying with the latest edition may put a product out of compliance with 60601-1 2nd edition, and so make a product unmarketable in regions that still adhere to the earlier version. Countries still mandating the 2nd edition include Japan, Australia, New Zealand and China.

The 3rd edition of IEC 60601-1 has not yet been adopted in China and no clear timetable exists. The Chinese GB 9706.1-2007 standard is however an endorsement of the 2nd edition IEC 60601-1. It is, therefore, generally not possible to obtain successful registration in China with products developed and documented solely to the 3rd edition.

As a result, many vendors are working to meet both versions in the same design, which requires additional effort.



FIGURE 3: To date only the US, Canada and the EU has adopted IEC 60601-1 3rd edition standards.

EFFECTS OF IEC 60601-1 3rd EDITION

MANAGING RISK

Risk management, now a vital part of the standard, is a multifaceted, multistep process. It begins with risk assessment, which itself is composed of risk analysis [identification of hazards and estimation of the effect of each hazard] and then proceeds to risk evaluation [deciding if risk control is needed, recording results in the Risk Management File]. Standard techniques such as fault-tree analysis are among those used, but the assessment is not limited to that approach.

After the assessment phase, the risk management process moves on to risk control. Here, options for managing the risk are evaluated, any risk-control measures are implemented, and the residual risk is assessed [some risks cannot be eliminated by design changes]. There is also risk/benefit analysis, as well as examination of the critical issue of any new risks that may result from the risk-control steps themselves.

The process concludes with an overall evaluation of the total original risk versus the remaining risk, determination if this is acceptable, and a formal risk-management report.

SOFTWARE

Changes in the 3rd edition IEC 60601-1 will affect the software too. As with any code-driven circuit, it will need to be validated for its basic design quality and thoroughness as well as its response to the unexpected or unlikely events.

EFFECT OF IEC 60601-1 3rd EDITION ON POWER SUPPLIES

In practice, the transition from IEC 60601-1 2nd to 3rd editions does not change the basic requirements on a power supply. The primary differences between the editions concern more the classification of the medical device than to changes in power system design.

MEANS OF PROTECTION – MOOP AND MOPP

The standard requires a device have two isolation barriers as means of protection [MOP] where the device may come into contact with a patient.

These can be a combination of basic safety insulation, use of protective earth ground, and isolation barriers that present a high-impedance path between input and output. In general, a supply that only incorporates MOOP is less expensive than one that also includes MOPP. However, demonstrating that the product and supply does not need MOPP is difficult, and adding it later is costly.

Both the 2nd and 3rd revisions require two mechanisms for guarding each in the event of a failure. For the area of basic electrical safety and avoiding shock hazard, the 3rd edition further divides means of protection into operator protection and patient protection. This is because the potential hazards seen by each can be quite different; an operator has access to a control panel, for example, while the patient may be "connected" via probes.

Therefore, there are means of operator protection [MOOP] and means of patient protection [MOPP], with different requirements for insulation, spacing, and isolation. Of course, it may be arguable if a particular circuitry function falls under MOOP or MOPP categories; the manufacturer needs to assess this and record it in the risk management file.

LEVEL OF PROTECTION

The changes in power supply classification from 2nd edition to 3rd edition deal with definition, not performance. For Type B applications, a non-medical-rated supply will be satisfactory, as long as it has reduced leakage currents below 500 μ A; this is true for "one MOPP" classifications. Type BF applications will be satisfied by a supply that is rated to IEC 60601-1, which will continue to satisfy "two MOOP" and "one MOPP" classifications. Type CF requires an IEC 60601-1 qualified supply, plus an additional isolation barrier between the supply and the applied part that touches the patient. Typically, this mandate is met with an isolation transformer or a dc-dc converter with 8 mm creepage and double insulation; this is true for the "two MOPP" classification. See figure 4 for a summary of these requirements.

2nd EDITION REQUIREMENTS BY CLASSIFICATION

Classifications	Isolation	Creepage	Insulation
Type B	1500 Vac	2.5 mm	Basic
Type BF	3000 Vac	5 mm	Double
Type CF	4000 Vac	8 mm	Double

3rd EDITION REQUIREMENTS BY CLASSIFICATION

Classifications	Isolation	Creepage	Insulation
One MOOP	1500 Vac	2.5 mm	Basic
Two MOOP	3000 Vac	5 mm	Double
One MOPP	1500 Vac	4 mm	Basic
Two MOPP	4000 Vac	8 mm	Double

FIGURE 4: IEC 60601-1 3rd edition requires differing levels of isolation, insulation, creepage, and leakage depending on the MOP level. When comparing the requirements to those of the 2nd edition standard, it becomes clear that the difference is in definition, not performance.

In general, a supply that only incorporates MOOP is less expensive than one that also includes MOPP. However, demonstrating that the product and supply does not need MOPP is difficult, and adding it later is costly, so it is best to initially go with a supply that meets both criteria.

FUTURE EFFECTS OF MOOP AND MOPP

Historically, medical power supplies have been completely analog [hardware circuitry only] with no software at all.

While digital power supplies haven't achieved mass scale adoption outside the server and telecoms industry, this will eventually change, especially since one MOOP applications can already use non-medical power components, such as CUI's Novum suite of digital dc-dc modules.

When the shift eventually happens for two MOOP and two MOPP products, designers will need to undergo static testing [including basic code walkthroughs, code inspections, algorithm analysis]; dynamic testing [for data synchronization, task

synchronization, and run-time issues etc); and finally formal testing [an academic-like approach using tools such as topology and set theory, to show that all requirements have been met, that the system will be stable, and that algorithms are built correctly and completely].

SUMMARY

The IEC 60601-1 standard is complex, and the 3rd edition is far more complicated, convoluted, and confusing than its predecessor. There are related and intertwined standards in addition to IEC 60601, including formal collateral standards, which are directly related “family” members. There are some standards for guidance alone, and some you need to both follow and be formally certified as meeting and complying. There are many areas of conflict, confusion, ambiguity, and “subject to interpretation.” The conflicting elements of the 2nd and 3rd edition standards, coupled with its slow and [to date] incomplete rollout, further complicate matters.

Simply shipping a medical device with basic documentation to a certification lab is no longer adequate. Comprehensive, carefully structured documentation is needed for the design analysis, the design process, and the design rationale with explanations for why certain elements were or were not included or undertaken.



FIGURE 5: The CUI medical power supply family (15~400 W) is certified for IEC 60601-1 2nd edition and 3rd edition two MOPP standards.

In order to help ease the compliance process for medical device designers, CUI offers a comprehensive line of [medical power supplies ranging from 15~400 W](#) that have been certified to IEC 60601 2nd edition and 3rd edition two MOPP standards.